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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

20855 7590 04/04/2002

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EXAMINER
BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/749,980	LEE, ELAINE	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-24, drawn to vaso-occlusive composition, classified in class 606, subclass 151.

   II. Claims 25-30, drawn to method of occluding an aneurysm, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product because there are many different compositions available that can be administered to occlude an aneurysm and the process only requires the use of the composition and does not require the use of the vaso-occlusive member.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Dahna S. Pasternak on March 5, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-30 are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. The abstract is too general, it does not contain enough information. The included abstract does not include the components of the composition nor does it include the methods that the composition will be utilized in.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The use of the trademark DACRON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 2 is objected to because the list within the claim has been misnumbered. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: change "and a material" to --and an additional material--. It is unclear that the material is in addition to the vaso-occlusive member. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the limitation "cytokine" in line 1. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 21 should be dependent upon claim 20 and not claim 19.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 11-14, 18-21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,980550 to Eder et al. Eder discloses a vaso-occlusive device as claimed. Referring to claims 1-4 and 18, Eder discloses a vaso-occlusive composition that includes a vaso-occlusive coil (column 3 lines 17-20), a thrombus-stabilizing molecule (column 6 lines 38-41), and a bioactive material in the form of cytokine VEGF (column 6 lines 38-48). Referring to claims 11-13, Eder discloses a device that has a bioactive material, a thrombus-stabilizing molecule or both the thrombus-stabilizing molecule and the bioactive material permanently bonded to the vaso-occlusive member (column 6 lines 38-48). Referring to claim 14, Eder also discloses a vaso-occlusive composition that has been plasma treated (column 3 lines 60-61). Referring to claims 19-21 and 24, Eder discloses a method to occlude an aneurysm by administering the vaso-occlusive composition (column7 lines19-23 and lines 48-59) by administering the bioactive material VEGF.

9. Claims 1, 5-6, 16, 19 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,096,052 to Callister et al. Callister discloses the claimed occluding device. Referring to claims 1, 5 and 6, Callister discloses a device that comprises a vaso-occlusive member and an additional material of copper (column 8 lines 20-28). Referring to claim 16, Callister discloses a device that is microtextured by sandblasting (column 8 lines 13-15). Referring to claims 19 and 22, Callister also discloses a method that administers the composition including copper to occlude a vessel(see claims 33-42 and column 8 lines 25-28).

10. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,894,022 to Ji et al. Ji discloses the claimed vaso-occlusive composition. Ji discloses a matrix base (Column 2 lines38-42) that cross-links fibrin(column 11 lines 65-67) to form a microscopic mesh (column 2 lines 53-56).

11. Claims1, 7, 8, 11, 17, 19 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,800,507 to Schwartz. Schwartz discloses the claimed vaso-occlusive composition. Referring to claims 1, 7 and 8, Schwartz discloses a composition that includes a vaso-occlusive member (column 4 lines 64-67) and thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44). Referring to claims 11 and 17, Schwartz discloses a composition that the material fibrin is adsorbed to the vaso-occlusive member (column 3 lines 60-64) and the vaso-occlusive member has a tie layer between the stent and the material fibrin (column3 line 60 - column 4 line 4). Referring to claims 19 and 23, Schwartz discloses a method that administers a vaso-occlusive composition including the thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44) to an occluded vessel (column 4 line 64 - column 5 line 5).

12. Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,891,192 to Murayama et al. Murayama discloses the claimed vaso-occlusive composition. Murayama discloses a vaso-occlusive coil subjected to ion implantation (column 3 line 21-22) and an additional material of fibrin (column 2 line 64 – column 3 line 8 and column 6 lines 2-4).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '190. Schwartz discloses the claimed device except for the use of plasminogen activator inhibitor-1 (PAI-1) or α_2-antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII,

PAI-1 and α_2-antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace Factor XIII (column 3 lines 47-48) with PAI-1 or α_2-antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to surface modifications:

U.S. Patent No. 5,932,299 to Katoot

U.S. Patent No. 6,033,582 to Lee et al.

The following patents are cited to show the state of the art with respect to vaso-occlusive compositions in general:

U.S. Patent No. 5,476,472 to Dormandy, Jr. et al.

U.S. Patent No. 5,653,727 to Wiktor

U.S. Patent No 6,080,190 to Schwartz

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
April 1, 2002

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700